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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,247	08/15/2006	Philippe Chavignac	SAIME 3.3-004	1734

530 7590 03/25/2010
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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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03/25/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,247	Applicant(s) CHALVIGNAC, PHILIPPE	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Action is in response the amendment filed 1/22/2010. No claims have been amended, added or cancelled. Thus, claims 1-16 are currently pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom (US 5,937,853) in view of Chalvignac (US 2002/0014239) and Ernst (US 3,961,627).

Regarding claim 1, Strom discloses a ventilator capable of operating in inhalation and exhalation phases, the apparatus comprising: an inhalation duct (4) and an exhalation duct (6), a pressure and flow rate sensor (10) associated with the inhalation duct (see Figure 1), and a regulating unit (14) that takes a first reference value input (see Figure 1) and a second input from the pressure and/or flow sensor (see Figure 1) such to allow real time transmission of a pressure or flow signal for determining barometric or volumetric mode operation (see column 4, lines 19-28) and controlling the operation of the gas source (see Figure 1).

Strom is silent as to inhalation and exhalation valves, the inhalation valve being controlled by an automatic control unit separate from a comparator and receiving signals from the sensors. Strom also does not give details as to the pressurized gas source (16). However,

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Chalvignac discloses a similar ventilator with a pressurized gas source (fan 12), an inhalation valve (16, 54) and an exhalation valve (32), the inhalation valve being controlled by an automatic control unit. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Strom's device with the controller, fan air source and inhalation/exhalation valves as taught by Chalvignac in order to deliver a constant flow of air to the patient as needed. Such a modification would involve simple substitution of a well known method for supplying gas into a well known system that would yield predictable results that do not patentably distinguish over the prior art of record. Furthermore, it appears as though the system of Strom would perform equally well with the fan and valve system of Chalvignac.

Strom/Chalvignac does not explicitly have an automatic control unit separate from the control means noted above. However, absent a critical teaching and/or showing of expected results from a separate controller for the valves and comparator, examiner contends that the number of individual control units is an obvious design consideration to one of ordinary skill in the art at the time the invention was made in order to have back up controls in case one breaks for example. Also, since Strom has a controller that directly controls the gas delivery unit and Chalvignac has a controller that directly controls the valves, it would have been obvious to keep the controllers operating as is in the modification and it appears as though the system would work equally well with separate controllers for the comparator and the valves.

Strom further discloses that the ventilator automatically switches between pressure and volume support (column 2, lines 35-40 and 48-65 and column 4, lines 19-28) and that the sensor signals are compared against threshold values (see for example column 5, lines 45-50) and the

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result is used to control gas delivery. This implies that Strom has a comparator and a switch.

However, to the extent that Strom does not explicitly disclose a comparator, Ernst teaches a selection means (comparator 7) capable of selecting a parameter of flow or pressure to define a gas related parameter (see col. 4, lines 5-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chalvignac to include a comparator/selection means as taught by Ernst in order to permit switching between volume and pressure based regulation (see Ernst col. 4, lines 36-44) using a well known method/device. As discussed above, which control unit controls the switch is an obvious design consideration absent a critical teaching and/or a showing of unexpected results. Additionally, Ernst teaches an automatic control unit 8 for controlling the selection means separate from any control of a gas source.

Regarding Claim 2, the inhalation valve of Chalvignac is operable to generate leaks (para. 0061, line 6).

Regarding Claim 3, the gas source of Chalvignac is a centrifugal fan turbine with an axial air intake and peripheral output (para. 0060, lines 1-5). Chalvignac does not disclose the inertia value/moment of inertia of the fan is 150 g*cm^2 . However, it would have been obvious at the time the invention was made to modify the inertia value/moment of inertia of the fan to be 150 g*cm^2 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding Claim 14, the structural elements recited are noted above with respect to claim 1. The instant method steps (including selection of volumetric mode and controlling the gas

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source) would have been obvious to one of ordinary skill in the art, upon seeing the modified Strom reference, because they would have directly resulted from use of the modified device.

Regarding Claim 15, Chalvignac discloses that no pressure difference exists between the upstream part and the downstream part of the ventilator shown in Figure 1 when the inhalation valve opens. Flow is also permitted through bypass pipe 18, which eliminates pressure differences.

Regarding Claim 16, control of the volume of gas delivered by the modified system is obtained by control of the rotation speed of a rotor of the gas source (para. 0027, lines 1-3 of Chalvignac).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, and Ernst as applied to claim 1 above, further in view of Whitwam (US Patent 5,307,795).

Regarding Claim 4, Strom as modified by Chalvignac/Ernst does not disclose a second flow sensor on the expiratory duct. However, Whitwam teaches a flow sensor 15 on an expiratory duct (col. 2, line 54, see Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the system of Strom/Chalvignac/Ernst to include a second flow sensor as taught by Whitwam so that the total expired volume from the patient can be measured.

Additionally, Strom/Chalvignac/Ernst does not disclose a comparison means for the flow rate sensors to compare the respective flow rates in the inhalation and exhalation ducts.

Whitwam teaches a comparison means 20 (col. 3, lines 5-15) for comparing the respective flow

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rates in the inhalation and exhalation ducts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the system of Strom/Chalvignac/Ernst to include a comparison means as taught by Whitwam so that the expired tidal volume can be measured using a well known means (col. 3, line 13).

Regarding Claim 5, Whitman also teaches processing means 23 (col. 3, line 15) operable to filter a difference between the respective flow rates in real time. The processing means is associated with the comparison means (Fig. 1).

Regarding Claim 6, the combination of Strom/Chalvignac/Ernst and Whitwam will have the processing means connected to the automatic control unit.

The modified Chalvignac system does not disclose a memory connected the processing means. Whitwam discloses a memory 24 connected to a processing means. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chalvignac/Ernst to include a memory connected to the processing means as taught by Whitwam so that flow rate measurements can be stored.

The addition of Whitwam's sensors and comparison means as noted above includes circuitry programmed to trigger a new inhalation phase when the filtered flow rate difference is higher than a pre-determined threshold (col. 1, lines 49-62).

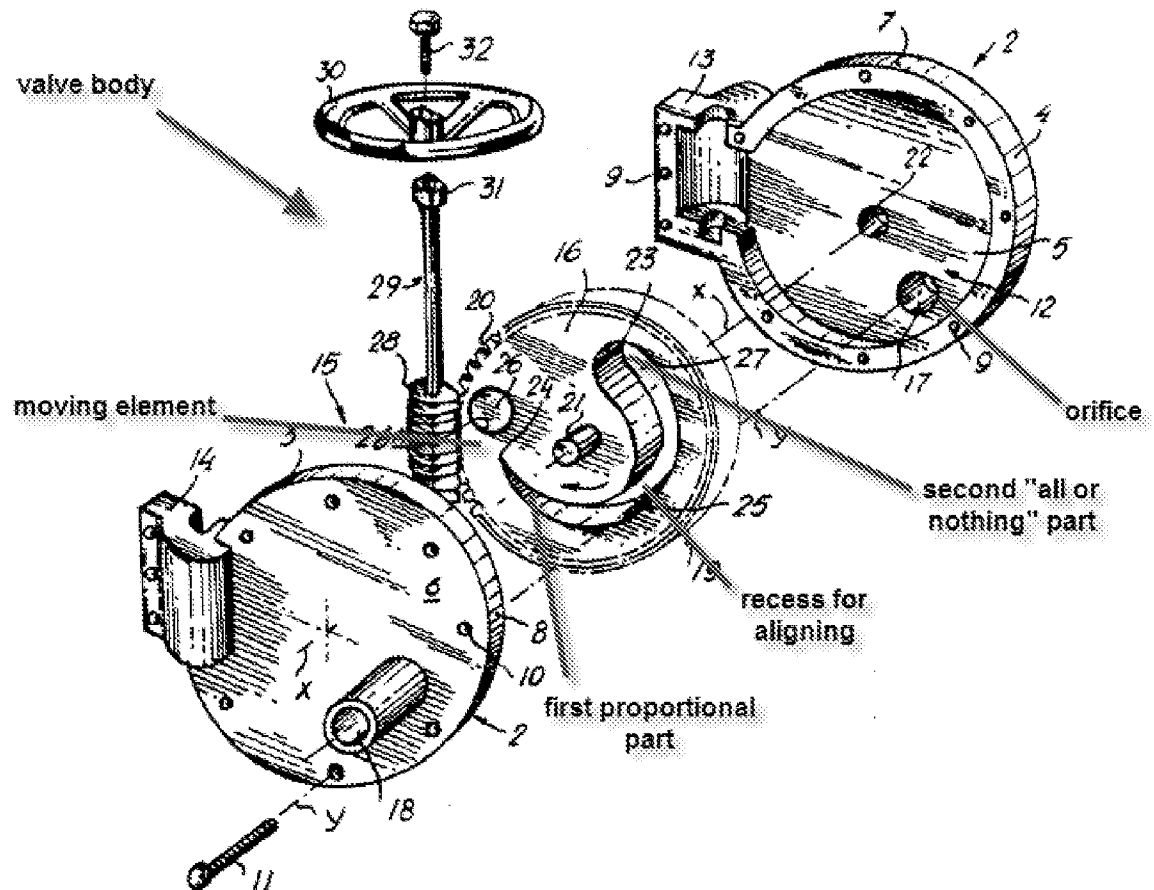
Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, and Ernst as applied to claim 1 above, further in view of Torres (US Patent 5,308,040).

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Regarding Claim 7, Chalvignac's inhalation valve 16 inherently has an orifice connected to the inhalation duct. This valve is a balloon valve, so it also appears to be operable to block the orifice in a closed position and partially free the orifice in an open position. However, Chalvignac does not disclose the valve comprising a recess for aligning with the orifice with the recess having a first part with a proportional operation and a second part with an all or nothing operation. Torres teaches a valve with a recess for aligning with the orifice with the recess having a first part with a proportional operation and a second part with an all or nothing operation, as shown below. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Chalvignac's inhalation valve in the modified Strom device with the valve as taught by Torres because both valve structures were well known in the art and substituting one valve for another would work equally well.

The first part of the recess shown below is triangular at the tip. The second part of the recess is not rectangular. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape to be rectangular because a mere change in shape is generally considered to be obvious to one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

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Regarding Claim 8, Torres's valve has the recess shaped so that when the moving element moves from the closed position to the open position, the first part is aligned with the orifice, and the second part is aligned with the orifice if the movement continues (clockwise motion in the figure above).

Regarding claim 9, the base of the triangle of the first part shown above would be parallel to one of the sides of the rectangular end of the recess shown above.

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Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, and Ernst, as applied to claim 1 above, further in view of Levin (US 5,813,410). The difference between instant claims 10 and 12 and the modified Strom/Chalvignac/Ernst device is a micro-turbine for controlling the exhalation valve. However, Levin discloses that micro-turbines are well known electrical energy generating means for assisting in driving various medical devices (column 3, lines 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a micro-turbine for providing the power needed to control the exhalation valve in the Strom/Chalvignac/Ernst device as taught by Levin in order to save energy by using the closed loop system's own flow to produce the power or to include a back-up means from controlling the valve in case of failure of other system components. Such a modification would involve a mere substitution of a well known method of providing power in a well known system that would yield predictable results that do not patentably distinguish over the prior art.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, Ernst, and Levin as applied to claim 10 above, further in view of DeVries (US Patent 6,102,038).

Regarding Claim 11, the modified Strom/Chalvignac/Ernst/Levin device is silent as to the micro turbine being directly connected to the expiratory valve with no element in between. DeVries teaches a balloon valve 32 (Fig. 1) directly connected to an air source 56 with no element in between. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chalvignac/Ernst/Levin to have

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the fan directly connected to the inhalation valve as taught by DeVries so that the valve can be easily controlled by slowing or accelerating the fan to deflate or inflate the valve. Furthermore, it appears as though the device would work equally well with the turbine being directly attached to the exhalation valve.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strom, Chalvignac, Ernst, and Levin as applied to claim 12 above, further in view of Tobia (US Patent 5,735,267).

Regarding Claim 13, Chalvignac discloses the gas source/fan operating constantly (para. 0060, line 4) and since flow is constantly flowing through the closed loop system the micro-turbine would also operate constantly.

The modified reference is silent as to the expiratory valve being controlled by selective connection of a pneumatic control line of the expiratory valve with the micro turbine. Tobia teaches an exhalation valve 26 that is a balloon valve (col. 4, line 36) that is controlled by selective control of a pneumatic control line 18 via flow control solenoid valve 16 (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Strom/Chalvignac/Ernst/Levine to include a solenoid controlling flow to the expiratory valve as taught by Tobia so that a controller can precisely control the inflation and deflation of the balloon valve.

Response to Arguments

Applicant's arguments filed 1/22/2010 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's arguments on page 9-10 against Strom are not persuasive because examiner admits that Strom lacks the valves and possibly the comparator but that is why the reference was combined with Chalvignac and Ernst. Additionally, examiner disagrees that Strom is not able to switch in real time between barometric and volumetric modes because the system of Strom allows real time transmission of a pressure or flow rate signal via the sensors to determine breathing parameters/efforts and then automatically switches between the various modes upon detection of apneas, for example (see abstract).

In response to applicant's argument that Strom is a completely different structure from Chalvignac and Ernst, examiner respectfully disagrees. All three references deal with ventilator control systems, which are in the same field of endeavor, and thus one of ordinary skill in the art could be motivated to look to the references when modifying Strom. Applicant's arguments that Chalvignac is a closed loop system are not commensurate with the scope of the claims because there is nothing in the claims requiring that the system be open. In addition, examiner notes that Chalvignac is used solely for teaching the use of inhalation and exhalation valves in ventilators for more accurately delivering a constant flow of air to the patient and for setting a positive

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pressure during the exhalation phase. Such a modification to Strom would involve the mere use of a well known method in a well known system to yield predictable results that do not patentably distinguish an invention over the prior art. With regards to Ernst, examiner notes that Ernset was cited merely for an explicit teaching that control systems operating between various modes and having threshold values have comparators and switches. What the controller actually controls (i.e., valves, gas sources, etc.) with the compared values is an obvious design consideration depending on the desired application of the device. For example, opening a valve for a certain time or speeding up a fan from a pressure source would both produce a change in delivered pressure, which way the change is produced from the sensed signals is a mere use of one known method for another to yield predictable results that do not patentably distinguish an invention over the prior art.

In response to applicant's argument that Levin is not connected to a valve and is in a different technical domain, examiner notes that Levin is disclosed merely for teaching that micro-turbines can be used in fluid flow systems to produce power for driving other medical devices. Since the device is in the medical field and solves the same problem of generating power from fluid flow to control other devices in the system, examiner contends that one of ordinary skill could be expected to find motivation from Levine for using a micro-turbine to generate the power needed to operate the valves in the modified fluid flow system of Strom. Use of the micro-turbine in the modified Strom device would involve mere substitution of a known method of generating power for another to yield predictable results that do not patentably distinguish an invention over the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771